

Ethics and Compliance
- A Compendium of Case Studies



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Foreword

The pharmaceutical industry operates in an increasingly complex legal and regulatory environment. As OPPI member companies having our holding companies and/or interests outside India, our business dealings are governed by local legislation as well as international laws, regulations & conventions, such as the FCPA, UK Bribery Act and the Anti-trust & Competition legislations. Most of us have our internal Ethics & Compliance Codes & Charters which enshrine the ethical principles governing our activities and we are committed to uphold the highest corporate ethics and strive for excellence. Integrity and acting ethically must be our pledge and commitment, as our industry touches new heights of growth with advanced medical knowledge and access to medicine.

While it is important to achieve results, how we achieve them is equally important. Being a patient-focused industry, we are committed to product safety and quality. In our interactions with the medical community, we are committed to follow ethical promotional practices. Integrity, accuracy and clarity are essential in our interactions and exchanges with our healthcare professionals and patients. Most importantly, there must always be confidence that prescription decisions are made on an ethical and patient-focused basis.

The OPPI Code of Pharmaceutical Marketing Practices 2010 is based on the model IFPMA Code and sets out principles considered basic to ethical behavior in pharmaceutical marketing. Its implementation can be meaningful only with the coordinated and coherent efforts of member companies with cooperation from the medical community.

As useful aid to the OPPI Code, our Ethics & Compliance Committee has put together a Compendium of case studies on Ethics & Compliance. Guidance and case studies on Competition law and Bribery & Corruption have also been included. The case studies covering various areas of compliance will provide practical guidance and suggestions on resolving ethical dilemmas which we are faced with in our day to day business activities. Success of the OPPI Code depends a lot on its implementation and we are confident that the Compendium will serve as a tool towards understanding and respecting the ethical principles and how to deal with situations that conflict with these principles.

Dr. Shailesh Ayyangar
Chairman, OPPI Ethics & Compliance Committee

Mr. Tapan Ray
Director General, OPPI



Case Study 1

Unethical Business Practices

Unethical Business Practices

Case

- ❖ John, a topper in the University, joined XYZ Company as a Territory Manager.
- ❖ Keith, the existing Territory Manager, had just been promoted as Area Business Manager of another territory, in recognition of his high sales achievement.
- ❖ John, inspired by Keith's high achievement and success, wanted to emulate him and sought guidance and coaching from Keith.
- ❖ John was, however, shocked when Keith introduced him to the actual market practices that he engaged in:
 - Keith told him that by using fake rubber stamps and fake letter heads of major institutions and important HCPs, orders could be generated through his personal computer.
 - Keith also introduced him to certain distributors who would be ready to place excessive orders, in return for sample packs of products being provided to them.

Unethical Business Practices

John's dilemma

- ❖ John reported these malpractices to Robert, his reporting Manager.
- ❖ To his surprise, Robert was aware of the unethical business practices and was himself conspiring with Keith to achieve sales targets by unethical means.
- ❖ He advised John that to sustain himself and grow in the organization, John should also follow the same trade practices.
- ❖ On joining XYZ Company, John had undergone the Ethics & Compliance training, based on which he reported the said malpractices to the Compliance Department and also handed over as evidences, the fake rubber stamps (distributors & Institutional head) and fake orders placed on major institutions & important HCPs.
- ❖ In the meantime, Robert started harassing John on other work related issues and pressurized him to resign.

Unethical Business Practices

Issues before the Compliance Department

- ❖ Unethical business practices.
- ❖ Fake & forged documentation generated by the employees to show inflated sales figures.
- ❖ Retaliation by Robert against John, the whistleblower.
- ❖ Violation of the Code of Ethics & Compliance Policy of the Company.

Unethical Business Practices

Investigation & Action

- ❖ The Compliance Department investigated the matter. The concerned HCPs, distributors, C&F depots & Institutional heads confirmed that the documents were fake and forged.
- ❖ John's information was proved to be true.
- ❖ The case and findings were placed before the Management, which directed disciplinary action to be taken against Keith and Robert in accordance with the Service Rules of the Company.
- ❖ In order to curb such malpractices, the Management put in place several SOPs providing checks and controls whereby the genuineness of documents would have to be certified by the Finance Manager of the Territory .
- ❖ A strong message was sent out to the Field employees to fully comply with the SOPs and Compliance policies declared by the Company and to uphold the highest standards of trade hygiene in future.



Case Study 2

Off-Label Promotion

Off-Label Promotion

Case

- ❖ A Company's drug approved for indication 'A' has new data published on its efficacy in an unapproved indication 'B', which has an unmet medical need.
- ❖ Some doctors used the drug for indication 'B' and found it to be effective in their patients with whom the existing line of treatment was not working.
- ❖ One of the Company's representatives decides to tap the potential of the drug for indication 'B' and started promoting the efficacy results as per the published data to doctors in order to increase sale of the drug.
- ❖ One of the Company's competitor brings this to the attention of the Industry Association and files a complaint of unethical promotion of the drug by the Company.

Off Label Promotion

Investigation by the Industry Association

- ❖ The Adjudication Committee of the Association investigated the complaint and held that the Company was found to have indulged in off label promotion of the drug.
- ❖ The Association Code on Marketing Practices prohibits off-label promotion of drugs. (Clause 3 of OPPI Code, 2010 & Clause 1.2 of the Uniform Code of DoP)
- ❖ The Company was also enjoined by the marketing approval given by the Drug Authorities to promote the drug in consistence with the terms of approval, viz., only for the approved indication.
- ❖ As per the Association Rules, the Company was directed to cease such off-label promotion and give a written undertaking for future compliance with the direction. by the company and is not permitted.

Off Label Promotion

Action

- ❖ As per the Association Rules, the Company was directed to cease such off-label promotion and give a written undertaking for future compliance with the direction by the company and is not permitted. Drugs can only be promoted to doctors for indications approved by the regulatory authority.
- ❖ On the Company's side, its Sales/Marketing functions were strongly warned against any off-label promotion of drugs, as the same would not only be in violation of the Industry Code but also of the terms of the marketing approval in respect of the drug.
- ❖ It was also highlighted to these functions that in western countries pushing of drugs for unapproved uses attracts criminal prosecutions and has resulted in convictions and hefty penalties.



Case Study 3

Relationship with Healthcare
Professionals

Relationship with Healthcare Professionals

Case

- ❖ A Company's Sales Rep is told by a doctor that he could significantly increase the volume of his prescriptions of one of the Company's products if the Rep was to arrange for him to attend conferences organized by the Company as a paid expert more often and to also arrange for the travel of his wife to accompany him.
- ❖ The doctor also told him that he would be willing to enter into a service contract with the Company for this purpose.
- ❖ The Rep replied that he would revert and conveyed the doctor's requests to his superior.

Relationship with Healthcare Professionals

Guidance

- ❖ The Rep was reminded that though the Company relies on healthcare professionals(HCPs) to provide expertise that is not available in-house, whether for conferences, publications or studies, the Company must have a legitimate business need for the services to be provided by the HCP. It is never appropriate to enter into a service contract with a HCP in order to influence prescriptions of the Company's product.
- ❖ No travel facilities can be extended to a HCP as a delegate, inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc., for self and family members for vacation or for attending conferences, seminars, workshops, CME programs.

Sponsorships

Guidance

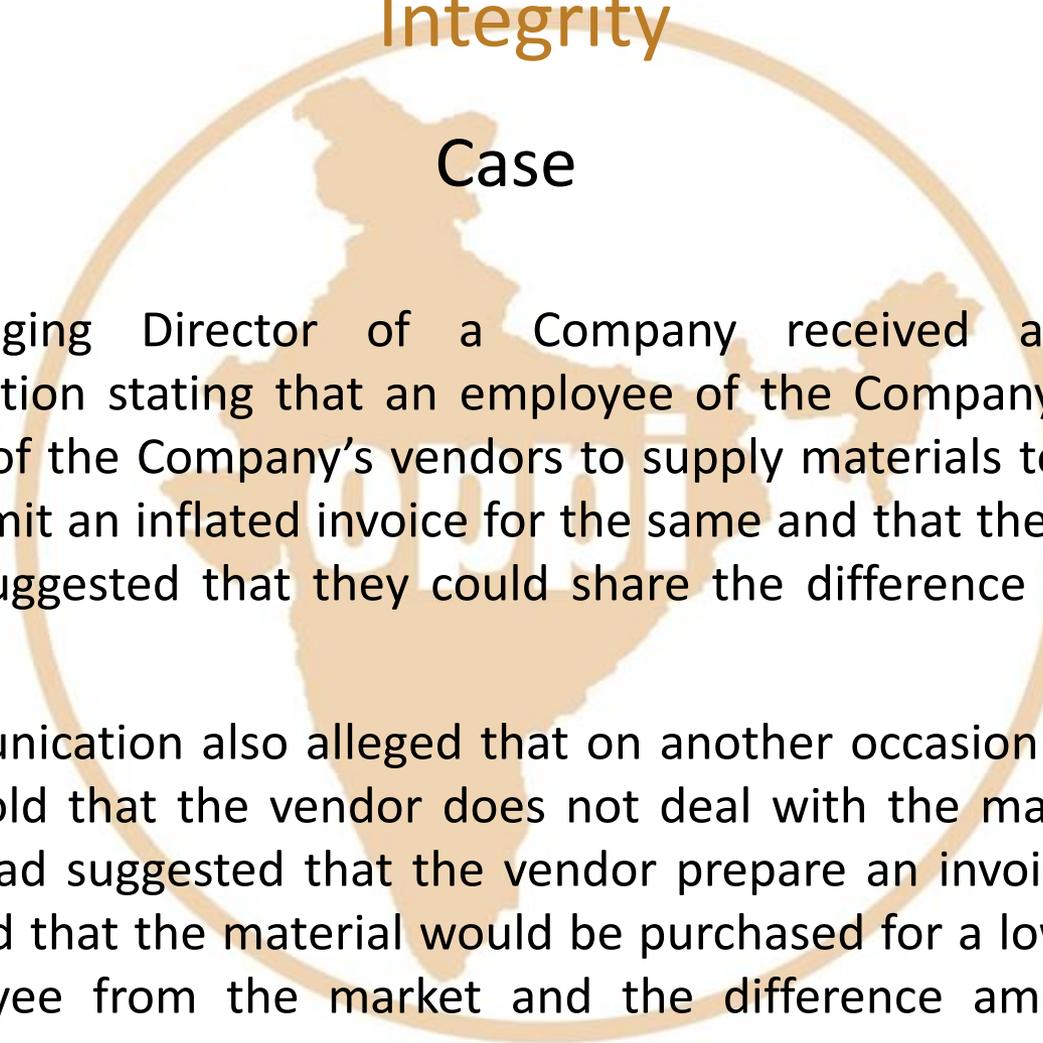
- ❖ It was also clarified to the Rep by his superior that payment of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, can be provided to HCPs who are providing genuine services as speakers or presenters, but not as delegates. Even in this case, the cost of travel of his spouse would not be borne by the Company.
- ❖ The doctor was politely informed that the Company could not bear the cost of his travel/accommodation as a delegate and his participation in any seminar, conference or CME would have to be at his own cost.



Case Study 4

Integrity

Integrity



Case

- ❖ The Managing Director of a Company received an anonymous communication stating that an employee of the Company had allegedly asked one of the Company's vendors to supply materials to the Company and to submit an inflated invoice for the same and that the employee had allegedly suggested that they could share the difference of the inflated amount.
- ❖ The communication also alleged that on another occasion the employee, on being told that the vendor does not deal with the material that was required, had suggested that the vendor prepare an invoice for a higher amount and that the material would be purchased for a lower amount by the employee from the market and the difference amount could be shared.

Integrity

Issues

- ❖ Although the anonymous message did not identify the employee allegedly indulging in unethical activities, the Company realised the possibility that such malpractices could exist which raised issues of :
- ❖ Misuse of authority to purchase
- ❖ Potential Conflict of interest
- ❖ Personal gain motives

Integrity

Actions

- ❖ The Company undertook a communication and training program on integrity and high ethical standards for all its employees to reinforce the message of integrity, zero tolerance of any breach thereof and disciplinary action including termination of service, for employees found dishonest & cheating.
- ❖ A list of approved vendors was drawn up and strictly applied.
- ❖ A system of two/dual approvers
- ❖ Only purchase dept to procure items required
- ❖ Due diligence as a matter of routine
- ❖ Random checks and monitoring to gain assurance



Case Study 5

Sponsorship

Sponsorship

Case

Sita, a Medical Rep, is visiting one of the most important KOLs in her region, Dr. Irani. It has taken Sita months to get this appointment. Dr. Irani is a long-time prescriber of a competitive product and Sita is desperate to come up with some ideas to get Dr. Irani to consider switching.

Dr. Irani heads the National Association of Nephrologists. She mentions to Sita that the professional association is hosting its annual meeting at a nearby hill resort in the following month. She suggests that if the Company could sponsor the Gala Dinner at the meeting, she would really appreciate it and such support would be very visible for the nephrology community. Dr. Irani informs Sita that there will be approximately 100 physicians and 100 non-physicians attending attending the dinner and the cost would be around Rs.10,000 per person.

Sponsorship

Issues

- ❖ The request for sponsorship is related to a meeting that will take place at a luxury resort in Himachal Pradesh.
- ❖ The request is for a social event, a gala dinner, and not for a substantive medical education session.
- ❖ According to the doctor, both physicians and non-physicians will be in attendance.
- ❖ The per person cost of the event is Rs.10,000/-, a rate that exceeds the normal policy of companies with regard to events.

Sponsorship

Action

- ❖ Sita was instructed by her superior to politely inform Dr. Irani that the Company would not be in a position to sponsor the dinner as requested as the same was prohibited by the Company's policy as also under the Industry Code and Govt. guidelines.

Sponsorship

Guidance

The primary purpose of any funds used to pay for meals or event expenses must be for promoting either a company's products or therapies or to advance medical education generally. Social events and entertainment are not permitted.

- ❖ When asked to provide support for a meeting or congress, always ask yourself the question, *“If this meeting agenda, location and cost were published in the newspaper, how would the general public perceive it?”*
- ❖ Any one of the following facts would be sufficient to prohibit such sponsorship:
 - Social event / Gala Dinner without scientific content
 - Luxury resort in Himachal Pradesh
 - Rs. 10,000/person
 - Attendance of non-HCPs



Case Study 6

Irregularities in Institutional Supplies

Irregularities in Institutional Supplies

Case

- ❖ Mr. A, an employee, reported to his Company an incident of unethical practice of false supply of medicines made to a Govt. Institution with 10% discount which was sold actually in the open market.
- ❖ Upon investigation, it was found that a false invoice in the name of the Institution was raised by one of the Company's distributors in collusion with the Area Manager for supply of a large quantity of medicines. The invoice included a 10% discount as approved by the Company on the specific Institutional order.
- ❖ On checking with the Institution it was found that it had neither ordered nor received the said medicines. False supply of the medicine to the Institution was shown to be made, when in fact the sale was made to another hospital for which no discount was approved.
- ❖ Discount @ 10% on medicines meant for sale to the Govt. Institution had been claimed by the distributor by submitting false documents.

Irregularities in Institutional Supplies

Actions

- ❖ As the reported irregularity was proved to be true, the concerned distributor was discontinued and the Area Manager's service was terminated.
- ❖ SOPs were put in place by which the price difference credit notes for the discount would require to be approved by someone outside the sales team, eg., the Finance Manager.
- ❖ The written purchase order of the Hospital / end-Institution and the proof of delivery would have to be checked for processing the price difference credit notes for discount.
- ❖ The Company would have a provision in its Distributorship Contracts for the right to information on the Company's products sold by them, and the right to access distributor's records, as and when required, to verify the information provided.
- ❖ The Secondary sales data provided by the distributor should be monitored and considered before processing the credit notes.



Case Study 7

Misuse of Funds under
CRM activity

Misuse of Funds under CRM activity

Case

- ❖ For a particular calendar quarter, three CRM programs were budgeted for a territory covering 15 doctors per program and the cost allocated was Rs. 7000/- per doctor towards local travel and hospitality.
- ❖ Bills raised by the transport agency and hotel and submitted by the Area Business Manager were paid by the Company.
- ❖ On a random meeting with one of the doctors the Regional Business Manager found that the said doctor had neither attended the CRM program nor was he invited to attend it.
- ❖ On checking with all the doctors, it was found that in each CRM program 4-5 doctors were falsely shown as participants and their cost was falsely charged to the Company by the agency/hotel in collusion with the ABM.

Misuse of Funds under CRM activity

Investigation

- ❖ It was decided to check with all the doctors listed for each CRM program, and it was found that in each CRM program 4-5 doctors were falsely shown as participants and their cost was falsely charged to the Company by the agency/hotel in collusion with the ABM.
- ❖ When the ABM was called by the RBM and questioned, he admitted his guilt and said that he would return the money he got from the travel agent and the hotel and requested that the Company be lenient with him.

Misuse of Funds under CRM activity

Actions

- ❖ Considering the serious nature of the ABM's dishonest acts, it was decided to terminate his services with immediate effect, which would act as a strong deterrent to other employees.
- ❖ It was also realized that adequate documentation was not maintained and nor were there enough controls in place to deter potential siphoning of funds with respect to the CRM activity.
- ❖ Strong SOPs and approval procedures were drawn up and put in effect in respect of funds to be used for CRM programs. Employees were directed to follow the prescribed procedures and through an appropriate communication they were cautioned that any breach of the same will attract disciplinary action.



Case Study 8

Promotional Material

Promotional Material

Case

- ❖ Shyam, a medical representative, found a very interesting article on the internet about the efficacy of a drug promoted by his Company. He decides to give print-outs of the same to the doctors of his territory. His doctors appreciated the article when he shared it with them . He is expecting to get a significant boost in his sales in coming months because of this information.
- ❖ He plans to share this article with his other colleagues.
- ❖ One of the doctors mentions this article to Shyam's ABM, who is surprised that Shyam has distributed the said article to doctors without checking with him.

Promotional Material

Issues

Shyam was called by the ABM and reprimanded for his action. The ABM reminded him that:

- ❖ The article will be considered as a promotional material & hence relevant laws /regulations (OPPI/Company internal policies) with respect to promotional material would be applicable to it.
- ❖ It may result in Off-Label Promotion which is a serious violation.
- ❖ It may result in inaccurate/unreliable product information sharing.
- ❖ It can jeopardize patient safety as well.
- ❖ It can violate copyright laws.
- ❖ Potential violation of local law and codes with respect to promotional material may result in legal action and penalty against the Company.

Promotional Material

Advice

- ❖ Only such promotional material must be used that has been approved by the Company and is in compliance with the law and the Industry code.
- ❖ No medical representative can hand out any material/information to any HCP on his own initiative.
- ❖ If a medical representative comes across any published articles or reports which could be useful to HCPs, he should first share the same with the Medical/marketing team and let them decide whether and how it can be shared further with any HCP.
- ❖ As a rule, no promotional material in the form of articles or reports should be used, unless it is approved by the people authorized in the Company.



Case Study 9

Hospitality, Gifts &
Entertainment

Hospitality/Gifts/Entertainment for HCPs

Case

Company X is organizing an International speaker event in Mumbai for their new product launch. To ensure good attendance in this high stake event, the marketing team proposes to:

- ❖ provide ground / air travel and hotel accommodation to attending HCPs from Mumbai and other cities.
- ❖ present a tie-pin and cufflinks as a brand reminder to all attending HCPs.
- ❖ organize a musical evening post the launch. The hotel was asked to build in the cost of the entertainment program in its bill.

Hospitality/Gifts/Entertainment for HCPs

Issues

- ❖ The Company's Compliance Officer pointed out to marketing team that Company's proposed actions may lead to compliance issues and a breach of the Industry Code and Govt. rules with regard to:
 - ❖ Travel/Accommodation Facilities to HCPs
 - ❖ Gifts
 - ❖ Entertainment alongwith a scientific event

Hospitality/Gifts/Entertainment for HCPs

Reminder

- ❖ No travel facility shall be extended to a HCP as a delegate, inside the country or outside , including rail, air , ship, cruise tickets, paid vacations etc. for self and family members for vacation or for attending conference, seminars, workshops, CME programs etc. (section 7.2 of the OPPI Code)
- ❖ No hospitality, like hotel accommodation, for self and family members under any pretext to be provided to a HCP except when the HCP is attending as a Speaker or Presenter. (section 7.5 of the OPPI Code)
- ❖ No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers etc. Gifts for the personal benefit of HCPs and family members, such as tickets to entertainment events, shall not be offered or provided. Providing entertainment alongwith a scientific event is inappropriate and not allowed.



Case Study 10

Samples

Samples

Case

- ❖ An HCP to whom a Company's oncology drug "X" is promoted, is a very good prescriber of the said drug. Since the drug is non - reimbursable and quite expensive, the HCP has requested the Company to provide one month's free therapy in the form of drug samples at quarterly intervals to certain patients directly. This would ensure that effective therapy cost to the said patients will come down.
- ❖ The Company has adequate samples of the drug to fulfill the request of the HCP.
- ❖ Before responding to the HCP, the Company's Compliance Officer is consulted.

Samples

Issues before the Company

- ❖ Can drug samples be used to bring down the cost of therapy ?
- ❖ Can drug samples be handed over to patients directly by the pharmaceutical company?
- ❖ Can samples be provided on a frequent basis ?

Samples

Reminders

- ❖ Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product. Samples must be handed directly to the person qualified to prescribe or the person authorized to receive the samples on their behalf.
- ❖ Samples may be supplied to HCPs in order to enhance patient care and should not be resold or otherwise misused. Samples are to be provided on an exceptional basis only and for the purpose of acquiring experience in dealing with such a product.
- ❖ Supply of such samples must be made in response to a signed and dated request from the recipient.
- ❖ Adequate system of control and accountability must be maintained.
- ❖ Product samples must not be used to reduce cost of treatment, provide discount, negotiate product inclusion in hospitals or formularies or to disguise commercial discounts.



Case Study 11

Bribery & Corruption

Bribery & Corruption

(Payment to Regulatory Agency Clerk)

Case

- ❖ When submitting a file for registration at the local authority, an employee of a consumer goods company made a small payment to the receiving clerk who accepts files and adds the same to the pile of files submitted by other companies for approvals.
- ❖ The small payment ensured that the company's file gets priority and will be taken up for consideration in a speedy manner. This is a common practice where a small payment is made to the person responsible for passing the file on for inspection and review.
- ❖ If the employee had not made the payment, it could have resulted in the file remaining at the bottom of the pile and thereby delaying the registration, the product and finally failure to meet the budget.
- ❖ When the employee put up a voucher claiming the payment under miscellaneous expense, his Finance Dept. raised a red flag.

Bribery & Corruption

(Payment to Regulatory Agency Clerk)

Issues

- ❖ This payment would be considered as facilitation payment to a Govt. official.
- ❖ It is not a valid defense that the payment does not affect the merits of the application, but only the speed with which it is reviewed.
- ❖ The company is committed to fighting all forms of corruption and no employee is expected to offer directly or indirectly money or any other benefit to a public official with a view to inducing him to do or not do something within the scope of his job/position.

Bribery & Corruption

(Payment to Regulatory Agency Clerk)

Guidance

- ❖ “Facilitation payment” is illegal and strictly prohibited.
- ❖ The Company must comply with anti-corruption/bribery legislation and conventions. In case it is an affiliate of a multinational company, any breach in India will also result in the parent company being liable for civil and criminal penalties, including heavy fines and prison sentences.
- ❖ The regulations apply also to indirect corruption, hence when dealing with contractors, look out for warning signs of potential corruption on their part. Pay particular attention to the contractor’s reputation (carry out a due diligence), avoid any large unsubstantiated advances asked by him, insist on invoices with detailed description of services and ensure that the level of remuneration for services is in line with the going rate for similar services.
- ❖ Early planning and regular discussions with the approval authority to meet launch date.
- ❖ Engage and lobby industry bodies to encourage greater efficiencies.



Case Study 12

HCP Interactions (Hospitality)

HCP Interactions (Hospitality)

Case

- ❖ A mini forum is to be organised where 11 doctors from a government hospital would be trained on dengue fever and receive the latest information on the subject.
- ❖ The doctors had all expressed how very busy they were and the only suitable time would be a weekend.
- ❖ The meeting is to be held over a weekend at a Spa Resort Hotel in Goa. The agenda shows $\frac{1}{2}$ a day of educational content. The remainder of the time is “free time”. The rooms are booked for Friday and Saturday nights. Family members are allowed to stay at nights and attend one of the meals. A total of 28 people are involved.

HCP Interactions (Hospitality)

Issues

The Company's Compliance Officer points out several concerns :

- ❖ There is a very high risk that this will be seen as offerings to a government official (which includes government doctors) and payment for favourable treatment which is in breach of the law.
- ❖ Although it is under the guise of an educational meeting, the nature of expenditure and activity is completely inappropriate.
- ❖ Note – it is not prohibited to hold educational meetings – but these must follow the SOP on Sponsorship of Healthcare Professionals.

HCP Interactions (Hospitality)

Reminders

❖ Per se, educational meetings are not prohibited

BUT

❖ They must be reasonable as per SOP on Sponsorship of Healthcare Professionals

❖ In arranging educational symposia – consider:

- Location
- Business reason for conference
- Type and number of delegates
- Duration of trip and balance of education/pleasure
- Suitability of entertainment/attendance of guests
- Standard of travel/accommodation
- Scrutiny of public eye - the newspaper test



Case Study 13

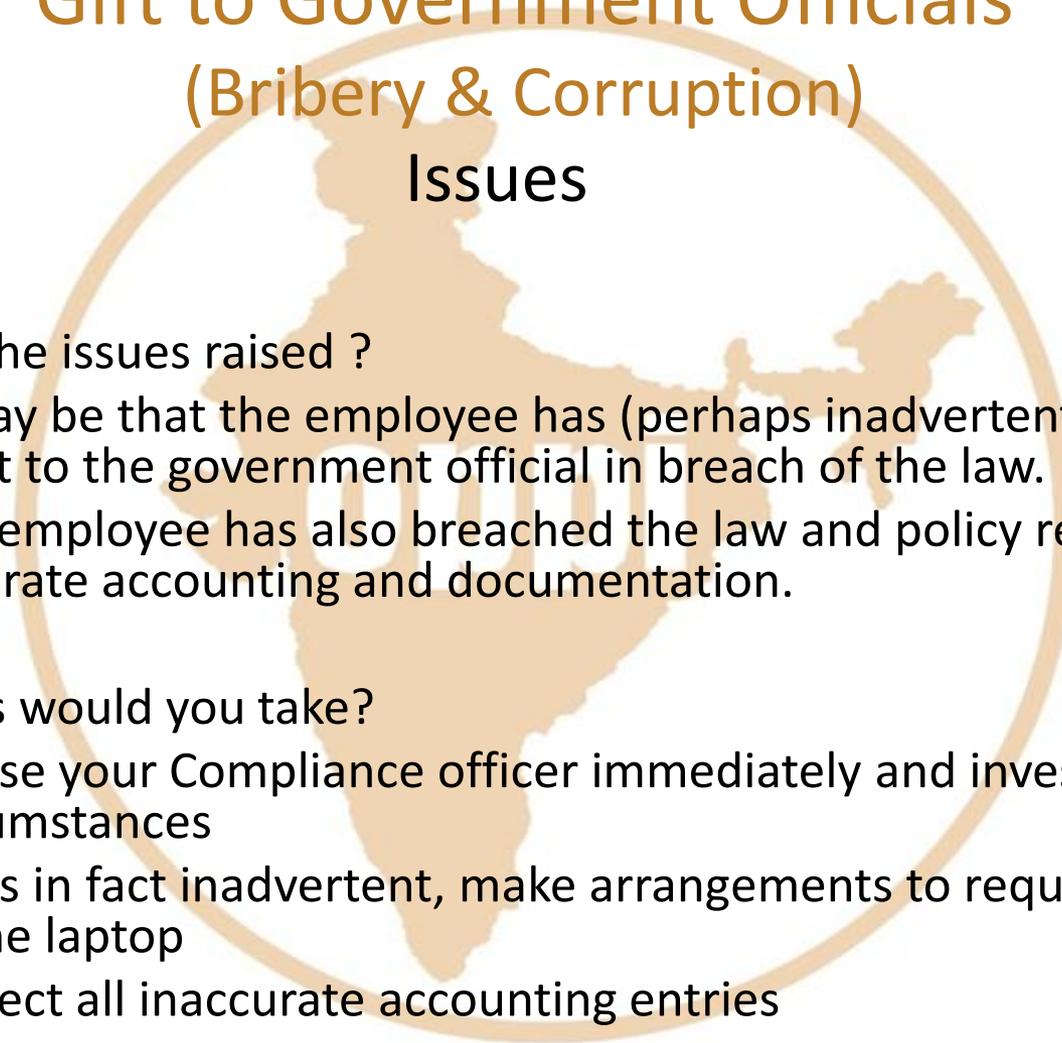
Gift to Government Officials
(Bribery & Corruption)

Gift to Government Officials (Bribery & Corruption)

Case

- ❖ During a yearly audit, it is discovered that one of the Company's procurement officers at a site gave a laptop computer to a govt. official in charge of auditing the site for compliance with environmental laws.
- ❖ Two weeks later, the Company's license application was approved.
- ❖ The employee requested reimbursement for the cost of the laptop, listing it simply as "equipment" on the reimbursement request.
- ❖ When questioned about this, the employee stated that the local official's computer stopped working on a site visit and to allow for the visit to proceed he provided the laptop. He was too embarrassed to ask for it back.

Gift to Government Officials (Bribery & Corruption) Issues



- ❖ What are the issues raised ?
 - It may be that the employee has (perhaps inadvertently!) provided a gift to the government official in breach of the law.
 - The employee has also breached the law and policy relating to accurate accounting and documentation.

- ❖ What steps would you take?
 - Advise your Compliance officer immediately and investigate the circumstances
 - If it is in fact inadvertent, make arrangements to request the return of the laptop
 - Correct all inaccurate accounting entries

Gift to Government Officials (Bribery & Corruption)

Advice

- ❖ In this case, before lending / giving the laptop computer, the officer should have considered whether
 - the same is justified for business reason
 - The same is reasonable
- ❖ Keep in mind that bribery does not have to take the form of a direct payment. It can take many forms (personal favors, promise to pay..) and be of anything of value. It is akin to 'you do something someone else wants → he is beholden to you'.
- ❖ Seek return of the laptop.



Case Study 14

Conflict of Interest (A)

Conflict of Interest

Case

There has been a vacancy in the Marketing Department of a Company since June 2010. It has been a long time, and Mr. L, the Marketing Head is unable to finalize any candidate suitable for this vacancy. Mr. N applied for this job and looking at his job application documents (he has completed his post graduation diploma in business management with specialization in Marketing from one of the renowned institutes in India and also has a 5+ years of experience) and after interviewing him, Mr. L finds him to be an excellent candidate and wants to give him a job offer.

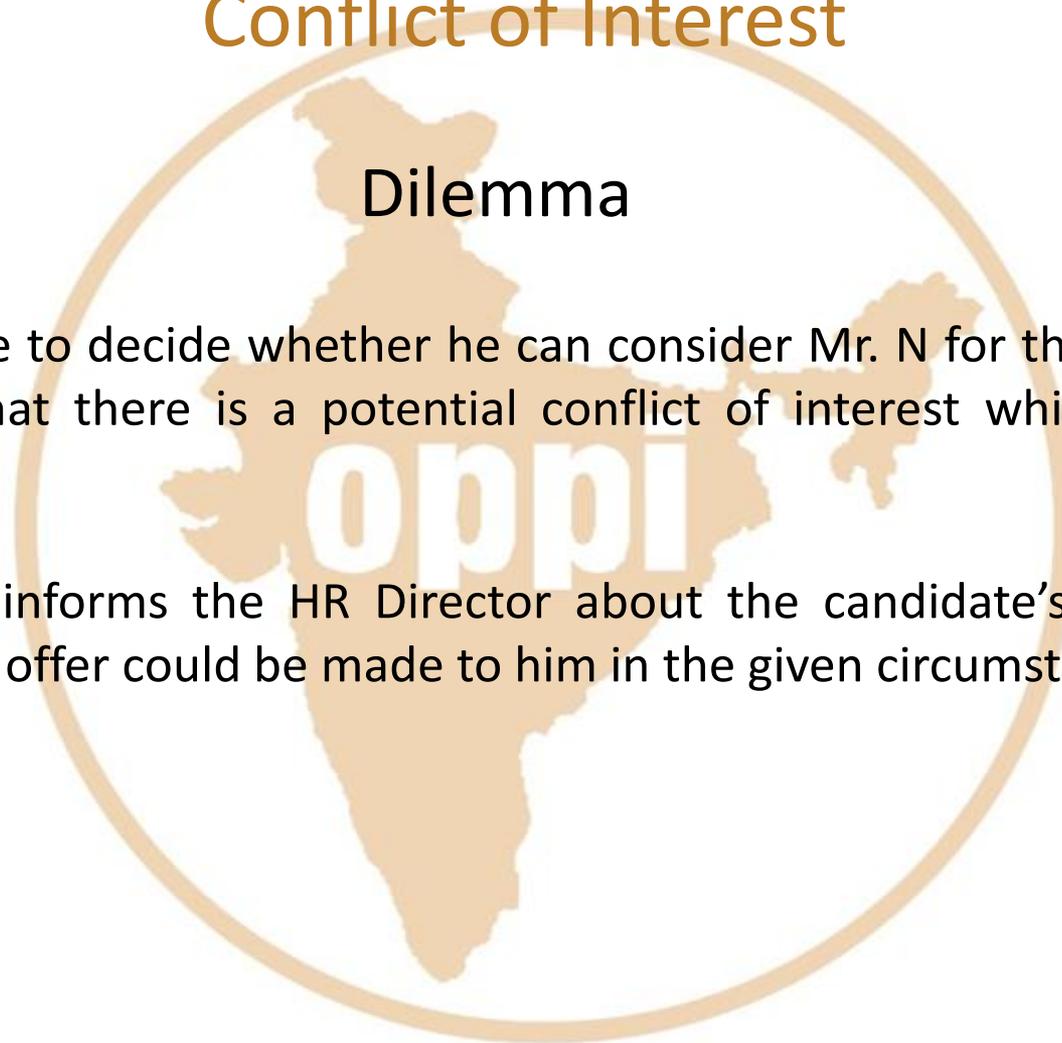
However, in the application papers, Mr. N has stated that his father is Director Procurement in one of the Government Hospitals which is an existing customer of the Company.

Conflict of Interest

Dilemma

Mr. L is unable to decide whether he can consider Mr. N for this job opening. He realises that there is a potential conflict of interest which may create problems.

He therefore informs the HR Director about the candidate's situation and whether a job offer could be made to him in the given circumstances.



Conflict of Interest

Advice/Action

The HR Director advises Mr. L that the application and the recommended job offer will be forwarded to the HCC Committee as per the Company's SOP on "Recruitment of Ex and Current Government Employees".

The final decision whether the selected candidate could be offered employment will rest with this Committee.

The Committee would take the decision objectively and transparently so as to safeguard against any potential situation of conflict of interest.

The Committee finally came to a decision that Mr. N could be offered employment on the strength of his excellent qualification and experience and the fact that his father is a Director of the Govt. hospital which is a good customer should not come in the way of such employment.



Case Study 15

Conflict of Interest (B)

Conflict of Interest

Case

Mr. L later got a call from Mr. N's father. While the talk was largely restricted to business with the Hospital, however at one point of time Mr. N's father made the following statement:

“Mr. L, you take care of my son and I will take care of your business here.”

Conflict of Interest

Issues

Would your decision change ?



Conflict of Interest

Advice

Yes, even though it is just an oral statement, it appears as a verbal commitment and hence not acceptable. This could lead to potential violations of Foreign Corrupt Practices Act, 1977.

Hence in this situation the Company should not go ahead with the appointment of Mr. N.



Case Study 16

Scientific Advisory Board

Scientific Advisory Board

Case

- ❖ Alex, Medical Advisor of XYZ Pharma Limited has determined that the therapeutic team has unresolved interpretation of data on a specific key trial outcome.
- ❖ He has proposed that the medical team put together an Advisory Board of medical experts in India for intensive data review and debate session with internal teams. This Advisory Board will meet at regular intervals.
- ❖ He shares the idea with his Management team. The Marketing head requests that he should be added to the Board along with influential HCPs.

Scientific Advisory Board

Issues

There are some important issues XYZ Pharma should keep in mind while constituting an Advisory Board

- ❖ Possibilities of Off-label promotion of products
- ❖ Possibility of pre-approval promotion of products
- ❖ Misuse of this forum for inappropriately influencing the HCPs for product prescriptions (travel / hospitality etc)

Scientific Advisory Board

Action

XYZ Pharma should ask following questions to decide whether they are taking a right step:

- ❖ Do we already have this information? What is the purpose? What does the agenda looks like?
- ❖ Is an Advisory Board the best way to get this information?
- ❖ How much time is XYZ Pharma “pushing” information out v/s “pulling” information in?
- ❖ How many advisors are being invited to achieve the purpose and is it appropriate? Why are these advisors the best advisors for the purpose of this Advisory Board?
- ❖ Why marketing head needs to be there in meeting? Who determines the composition of an Advisory Board in XYZ Pharma? What does decision maker thinks about presence of influential HCPs?
- ❖ What material will be distributed to Advisory Board members?
- ❖ Are contracts being planned for clearly specifying roles, responsibilities, confidentiality and compensation?
- ❖ What are the details of event like funding, venue, travel, hospitality?



Case Study 17

Competition Law

Competition Law

Case

- ❖ In a recently held meeting of Marketing Committee of an Industry Association, one of the items on the Agenda was Government Tenders Procedure. The Association wanted to represent before Govt. what are the practical difficulties/problems which companies face such as timelines, documentations, supply commitments etc.
- ❖ Few members in order to counter the Govt.'s stand, shared some strategies with the hope that Govt. may change the terms of pricing and payment to make them more Industry friendly.
- ❖ Few enthusiastic attendees ended-up in discussing the strategy for mutual understanding while applying for Govt. Tenders so that no Company would suffer while applying for the Tenders.
- ❖ It was never the intention of the Association to develop a collective strategy in respect of Pricing and payment terms for Govt. Tenders.
- ❖ As issue was sensitive, other members present at the meeting did not participate in the discussion and even requested that such discussion be stopped forthwith but did not leave the Meeting.
- ❖ After a few days, a news item appeared in a leading Newspaper of the Country stating that Members of the Association decided to form a cartel for pricing in respect of Govt. Tenders. The news stated the names of the companies and their representatives who attended the said Meeting
- ❖ Government / CCI ordered a detailed inquiry regarding the above and asked the Association as to why this should not be considered as a violation of Competition Law.

Competition Law

Issues

- ❖ Discussion of a few Members regarding a mutual understanding to benefit each other in the Tender process and a few members' discussion regarding common strategies to change the Tender's terms in respect of pricing and payments, could be perceived as an intention of all the members present and even as the intention of the Association
- ❖ Reputation loss to image of the Association and the companies whose names appeared in the Newspaper.
- ❖ Penal action against all the companies represented at the Meeting and the Industry Association.

Competition Law

Advice

- ❖ Dissenting Members should object to the discussion and leave the meeting immediately if the discussion continues about such mutual understanding /common strategies in respect of pricing and payment terms relating Govt. Tender Process. Such dissenting members should ensure that their reason for leaving the meeting is recorded in the Minutes of the said Meeting
- ❖ Members being unaware that any such behavior could be considered as a violation of Competition Law is not an acceptable defense as Ignorance of Law is no excuse. It is strongly recommended that regular training for employees on Competition Law is a must inter alia any other laws concerning their work area.
- ❖ Strict action should be taken against all those employees who do not take such compliance trainings/courses seriously.
- ❖ Employees involved in such irresponsible behaviour should be sacked for their non-compliant behavior by the respective member companies and Management of the Association should also put forth this episode as a lesson for others so that they will give due importance to compliance training / courses provided by companies to its employees. The message would also go clearer to the Government that Association and Member companies are law abiding and take stern action against their erring employees.



Case Study 18

Fraudulent Institutional
Supplies

Fraudulent Institutional Supplies

Case

The Compliance Officer received an anonymous e mail complaining about irregular sales in the name of institution supplies. The issues raised in the complaint were as follows:

- ❖ In 2011, special discounts of 45% were sanctioned for bulk supplies of Topamin to Wellness Cooperative Charitable Institution (WCCI).
- ❖ A few sales employees in Gujarat, diverted these discounted stocks to the trade markets by raising false institutional orders and invoices.
- ❖ Many employees in Gujarat could not achieve their sales targets because of the availability of low rate of Topamin in their local trade markets.
- ❖ Some of the employees even lost their jobs due to non achievement of targets.

Fraudulent Institutional Supplies

Issues

- ❖ In the enthusiasm to achieve high performance some employees may succumb to the temptation of adopting such short cuts.
- ❖ Distributors/Trade partners may provide wrong information in order to take extra discounts in the name of institutions and make more profits by selling these stocks in trade markets.
- ❖ The staff of the Institution may stealthily siphon stocks to trade markets at lower prices.
- ❖ Some non performing employees may vindictively try to malign the reputation of high performing genuine employees.

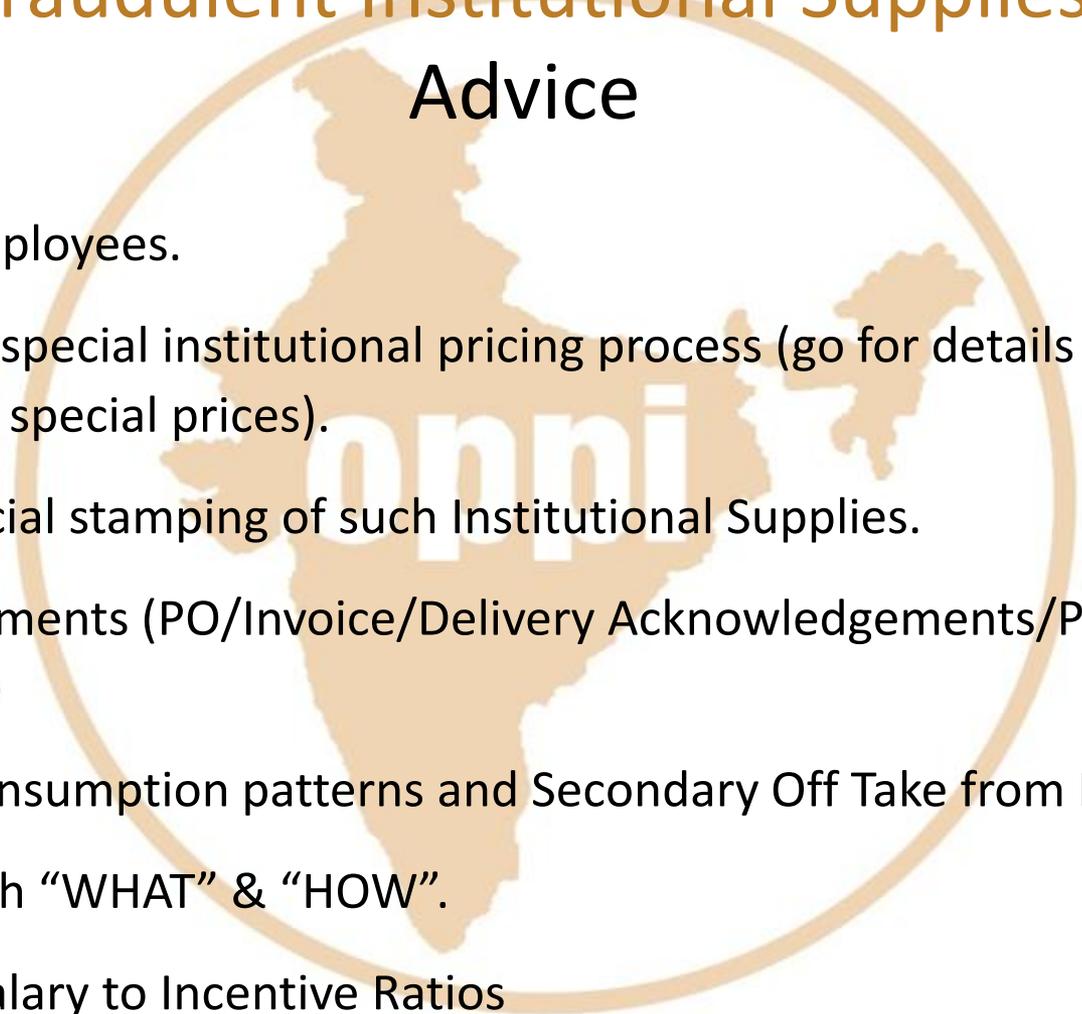
Fraudulent Institutional Supplies

Advice

- ❖ Validate the authenticity of bulk supplies of Topamine to Wellness Cooperative Charitable Institution (WCCI) by checking:
 - Purchase orders from WCCI
 - Invoice copies
 - Delivery Challans & Acknowledgements
 - Payment details from the institution (WCCI)
 - Consumption patterns of WCCI
 - Special Institutional Stamping
 - Credit Note Documents
- ❖ Study deviations, if any, in the trade sales pattern of Gujarat Trade Distributers and draw correlations if any, with the timing of Topamine supplies to WCCI.
- ❖ Study Exit Reports and performance records of employees who left the organization in 2011. (reasons for separation)
- ❖ Study consistency of performance track records of the employees who have been named in the complaint.

Fraudulent Institutional Supplies

Advice



- ❖ Educate employees.
- ❖ Strengthen special institutional pricing process (go for details before sanctioning special prices).
- ❖ Ensure special stamping of such Institutional Supplies.
- ❖ Verify documents (PO/Invoice/Delivery Acknowledgements/Payment Details etc.)
- ❖ Monitor Consumption patterns and Secondary Off Take from Institutions.
- ❖ Reward both “WHAT” & “HOW”.
- ❖ Balanced Salary to Incentive Ratios

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The overarching objective of the Ethics & Compliance Committee of OPPI is to review and evaluate the compliance within the Pharmaceutical Industry and recommend solutions and programs so as to enhance its ethical image. Towards this endeavour, OPPI member companies shared their Case Studies on Ethics & Compliance for learnings of the Compliance Managers, as well as other professionals.

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